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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/734,155 | 12/15/2003 | Nicholas A. Sceusa | SCEUSA3A | 2090 |

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| EXAMINER | |
|---|---|
| PAK, JOHN D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/734,155 | SCEUSA, NICHOLAS A. | |
| | Examiner | Art Unit | |
| | JOHN PAK | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-11 are pending in this application[1].

Applicant's election with traverse of Group I, wherein the single disclosed species of the "metal ion" is a mixture of zinc and copper, in the reply filed on 3/4/2005 is acknowledged. Applicant's traversal appears to be based on the argument that all of the claims can be searched and examined without serious burden. The Examiner cannot agree. The previous Office action (2/10/2005) set forth the reasons for the serious burden, which reasons are incorporated herein by reference. In short, the search and examination relevant to a disease condition such as impetigo (Group I) would not be coextensive with rhinitis (Group II) or Herpes virus infection (Group III). Each disease would have to be separately searched, the different prior art collections would have to be separately reviewed, and three separate analyses and rationale would have to be provided for each disease type. In view of the burden posed by the breadth of the claims ("metal ion") for just one invention, the additional search and examination burden for the other invention(s) would be undue. Applicant does not traverse the distinctness of the inventions; and therefore, the restriction requirement is still deemed to be proper. The restriction requirement is thereby maintained.

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[1] The restriction requirement in the Office action of 2/10/05 mistakenly referred to claim numbers from the counterpart PCT application, PCT/US04/07489. The inventive concepts were correctly identified but wrong claim numbers were assigned to each group. Group I in the U.S. application (instant case) restriction requirement should have been claim 3; Group II should have been claim 4; and Group III should have been claim 5. Linking claims should have been claims 1-2 and 6-11. Applicant appears to have understood the restriction requirement and the intended claim groupings since Group I is directed to

Accordingly, claims 1-3 and 6-11 will presently be examined to the extent that they read on the elected subject matter of Group I (i.e. the animal to be treated suffers from an autoimmune disease which causes secretions and eruptions via the calcium cascade). Claims 4-5 are withdrawn from further consideration as being directed to non-elected subject matter.

With regard to applicant's election of species (zinc + copper), the following comments are noted. A method of inhibiting the calcium cascade comprising administering to an animal in need of treatment for the bullous form of impetigo an effective amount of mixture of zinc and copper metal ions to block the calcium cascade is deemed to be allowable. The examination of the claims shall now proceed with an expanded species scope, i.e. zinc or copper as the metal ion species.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for metal ions that have antimicrobial activity, which are administered to an animal that has a condition with an underlying or

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the same concept of treating animals with an autoimmune disease which causes secretions and eruptions via the calcium cascade.

concomitant microbial etiology, such as for example the bullous form of impetigo, does not reasonably provide enablement for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to a broadly defined mechanism (inhibit the calcium cascade) by which any animal suffering from an autoimmune disease which causes secretions and eruptions via the calcium cascade is effectively treated. It is not stated in the claims whether the secretions and eruptions are internal or external. The claims are extremely broad as shown below.

| Diseases encompassed | Active agents | Mode of administration |
|---|---|---|
| The elected invention is "autoimmune disease which causes secretions and eruptions via the calcium cascade.<br><br>The specification only mentions the bullous form of impetigo.<br><br>Other diseases could include lupus, scleroderma, inflammatory bowel diseases, psoriasis, autoimmune hepatitis, bullous pemphigoid, and many other diseases. | Claim 1: "a metal ion that blocks the calcium cascade"<br><br>Claim 2: Zn, Cu, Mg, Mn, Fe, Al, mixtures thereof | Claim 1: not specified<br><br>Claim 6: nasal cavity<br><br>Claim 7: through the mouth into the nasal cavity |

The state of the art in treating various autoimmune diseases is that such diseases are some of the most difficult diseases to treat. There is no common treatment that is effective for many different types of autoimmune diseases. Here, the diseases encompassed are divergent and are not known to be treated with one common type of medicine.

Even though the relative skill of those in the art is quite high given the medical degree necessary to practice medicine and treat patients with serious conditions as the above discussed autoimmune diseases, the unpredictability in the art is also quite high due to the inability of science to find an effective treatment for the individual diseases, let alone a common treatment for all such diseases.

Unpredictability related to nasal or mouth-nasal cavity modes of administration is even higher. For example, impetigo is an infection of the skin. The claims read on nasally administering metal ions, or delivering metal ions across the mucous membranes of the mouth into the nasal cavity. In addition to the unpredictability involved for the reasons stated above, further unpredictability would result from such indirect administration of the metal ions.

In this context, the provided specification direction or guidance is quite sparse. Even though the same broad language as the claim language is used throughout the specification to describe the invention, no specific objective experimental result is provided to show that the metal ions of the invention, delivered via the nasal cavity or

otherwise, would treat an animal "suffering from an autoimmune disease which causes secretions and eruptions via the Calcium cascade." Given the state of the art, the variety of divergent diseases encompassed by the claims, and the other factors discussed above, in the absence of any working examples one skilled in the art would be faced with undue experimentation in order to practice the invention to the full extent claimed.

Therefore, the claims are rejected as lacking in adequate enabling support.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kashirina in view of Mandell et al.

Kashirina explicitly discloses treating impetigo vulgaris and impetigo streptogenes with 10% syntomycin/zinc paste (translation page 2). 763 children were effectively treated clinically (translation page 3, lines 15-19).

Mandell et al. teach that the bullous form of impetigo comprises about 10% of all cases of impetigo (page 911, paragraph bridging left and right columns).

It is recognized that "inhibiting the calcium cascade" and "autoimmune disease which causes secretions and eruptions via the calcium cascade" features are not stated in verbatim language by Kashirina. However, applicant's specification is evidence that "blistering eruptions running sores such as the bullous form of impetigo" fall within such autoimmune disease, in the context of applicant's invention (see specification, page 6, paragraph 0019). Kashirina's patients had "oozing lesions," which were stopped by the zinc-containing paste (translation page 2, last two lines and the paragraph bridging translation pages 2 and 3). Hence, Kashirina's patients clearly had the type of bullous form of impetigo, which is readable on the instant claims. Further, because the same metal, zinc, was administered to the same patients for the same disease at dosage that cannot be distinguished, the same result of inhibiting calcium cascade must necessarily have been obtained.

For these reasons, one of ordinary skill in the art would have been motivated to treat the bullous form of impetigo with Kashirina's zinc-containing composition.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).